REMARKS

I. Status of the claims

Claims 1-3, 17-19, and 21-22 are pending.

Claims 1-3, 17, 19, and 22 are amended

Claims 4-16, and 20 are withdrawn reserving the right to prosecute them in continuing or divisional applications.

II. Support for the Claim Amendments

"Plurality" and "more than one peptide" are in the specification in at least the following locations:

Page	***Lines***
2	26-28
3	5-7 and 17, 20
7	4-5
12	9
13	15
21	19-32

There is also an example of a plurality of peptides for *H. pylori* detection (FIGS. 6, 7, Example 1)

"Arrays" are in the specification in at least the following locations and could be used in claims.

Page	***Lines***
3	2,5

Peptides of 5-10 amino acids are described in at least the following locations

Page	***Lines***
3	9-10

III. An Expert Declaration from Dr. Anderson Showed Why Regenmortel Should be Removed as a Basis for Rejection

Applicant is dismayed that even after the extensive interview of April 21, 2004 in which the examiner, SPE Le, the inventor, Mr. Lazarus and the undersigned representing the applicant, discussed why Regenmortel does not teach all the claimed elements and does not satisfy the legal requirement for an anticipation rejection, the examiner persists in maintaining this rejection.

A Declaration under 37 C.F.R § 1.132 by Dr. Byron Anderson, an expert in the field of immunology, was appended as Exhibit A in the Response of July 16, 2004. His *Curriculum Vitae* was Exhibit B. As Dr. Anderson testified, mimotopes as reviewed by Regenmortel, "are not proteins or peptide sequences derived from proteins" (Exhibit A, par. 4a) (any homology of a mimotope sequence to a protein sequence is by chance only). Furthermore, Dr. Anderson testifies that the mimotopes of Regenmortel "cannot be defined as a comparative protein as the examiner has done...." (Exhibit A, par. 4a).

Dr. Anderson testified that the present invention is "unique and inventive," (Exhibit A, par. 4b) and is "a contribution to the field of immunology." (Exhibit A, page 6)

Regenmortel expressly defines his own review as of the:

> Steadily increasing ability to identify antigenic sites in viral proteins and then to design linear peptides that mimic the three-dimensional conformational features of key immunodominant sites in viral proteins.

Note that mimotopes are synthetic peptides designed to mimic a 3-D composition.

> Such molecular libraries often contain peptides that bind to the appropriate antibodies but show no sequence similarity with the viral proteins that the peptides correctly mimic in a functional sense. Such epitopes are called mimotopes because they are thought to mimic discontinuous epitopes of the antigen.
>
> Regenmortel, p. 334.

Regenmortel is limited to "viral proteins."

Claim 1 is not limited to synthetic peptides, which, according to the examiner, is taught in Regenmortel (Action page 2, par. 2). Also, unlike mimotopes, the peptides of the present invention have amino acid sequences that are the same as part of the target protein sequence.

All pending claims in the present application relate to claim 1. Claim 1 is amended herein to recite a "plurality" of peptides as described in the specification, but the elements are the same as original claim 1. The examiner's attempts to force parts of Regenmortel into a shoe that doesn't fit, *i.e.,* claim 1, is illustrated below and testified to as incorrect by Dr. Anderson (Exhibit A):

Elements of Claim 1	The Examiner's Selection from Regenmortel (Action pages 2-3)
immunogenic peptide	mimotopes, mimotope 13
target protein	viral protein, HbsAg, HCV 35-47
comparative protein	mimotopes, HCV, mimotope 17, 14 or P715c

There are target proteins, immunogenic peptides with a portion of the target protein sequence, and comparative proteins in claim 1.

In contrast, Regenmortel only has "mimotopes" and viral antigens. There is no correspondence with the three elements of claim 1. "Mimotopes" are used for two separate elements of claim 1. Therefore, by definition Regenmortel does not anticipate claim 1.

The examiner relates his mimotopes both to "peptides" and to "comparative proteins." In the example given on page 3, "HbsAg" is the target, HCV the "comparative protein."

The examiner equates "HCV 35-47" to a target protein and mimotope 17 or mimotope 14 as a comparative protein. (According to the examiner a "comparative protein" is a "non-target protein having less that 50% homology") as well as designating "mimotope 13" as a "peptide" but this mimotope is not derived from a target protein.

If the examiner thinks mimotopes are analogous to claim 1's "target protein," that would teach **away** from the present invention because the peptides of claim 1 **expressly** show sequence similarity to a target protein, whereas the mimotopes of Regenmortel by definition show dissimilar sequences.

The examiner misreads the claimed application because the comparative proteins are compared with the "immunogenic peptides" not to the target proteins [(see claims 1(c))]. The comparative proteins are **NOT CLAIMED**. The preamble clearly defines "a plurality of peptides" as the claimed composition.

Applicant would consider deleting either step a or e if that would facilitate allowance.

The court in *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332 stated:

"In general, a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 62 USPQ2d 1781, 1784 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc., v Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)).

"[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the inventions so defined, and not some other, is the one the patent protects." *Bell Communications Research, Inc. v. Vitalink Communications Corp.,* 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention. See, *e.g., Electro Sci. Indus. v. Dynamic Details, Inc.,* 307 F.3 1343, 1348, 64 USPQ2d 1781, 1783, (fed. Cir. 2002); *Rapoport v. Dement,* 254 F.3d 1053, 1059, 59 USPQ2d 1215, 1219 (Fed. Cir. 2001); Pitney Bowes, 182 F.3d at 1306, 51 USPQ2d at 1166. On the other hand, "if the body of the claim sets out the complete invention," then the language of the preamble may be superfluous. *Schumer v. Lab Computer Sys., Inc.,* 308 F.3d 1304, 1310, 64 USPQ2d 1832, 1837 (Fed. Cir. 2002); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.,* 246 F.3d 1368, 1373-74, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001).

The court in *Pitney Bowes, Inc. v. Hewlett-Packard Co.,* 182 F.3d 1298 stated:

If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is "necessary to give life, meaning, and vitality" to the claim, then the claim preamble should be constructed as if in the balance of the claim. *Kropa v. Robie,* 38 C.C.P.A. 858, 187 F.2d 150, 152, 88 U.S.P.Q. (BNA) 478, 480-81 (CCPA 1951); see also *Rowe v. Dror,* 112 F.3d 473, 478, 42 U.S.P.Q.2D (BNA) 1550, 1553 (Fed. Cir. 1997); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.,* 868 F.2d 1251, 1257, 9 U.S.P.Q. 2D (BNA) 1962, 1966 (Fed. Cir. 1989).

IV. Because Rejections Based on Regenmortel are Faulty, Regenmortel Must be Removed as a Basis for the 103 Rejections

Claims 18-19 were rejected as obvious over Regenmortel and Hasegawa. Claim 22 was rejected as obvious over Regenmortel and Tu.

Because, as shown in Section III herein, and the Declaration Under 1.132 (Appendix A) that Regenmortel does not teach the peptides of the present invention, these rejections must fall also.

Hasegawa merely teaches adjuvants. There is no teaching or suggestion to combine Regenmortel and Hasegawa. Even if Regenmortel and Hasegawa were combined, the combination does not render claims 18-19 obvious because neither Regenmortel nor Hasegawa teach or suggest a plurality of immunogenic peptides that fits the description of claim 1.

On page 5 of the Action, the examiner states that Regenmortel in view of Tu (US Pat 5674483) renders claim 22 obvious. Tu merely teaches a method of administering IL-12 to reduce inflammation. IL-12 is a "heterodimeric cytokine" exceeding the limits of claim 1 (Howard *et al.* Chap. 20, Fundamental Immunology)

In *Nursery Supplies*, the court held:

> One **cannot simply backtrack from the invention to find a connection** to the prior art. Hindsight must be avoided. See *W.L. Gore and Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). Rather, **one must start with the prior art and find some suggestion or motivation either in a single reference** to modify it to produce the claimed invention, or some suggestion or motivation in a group of references to combine them to produce the claimed invention. *Nursery Supplies v. Lerio Corp.*, 45 U.S.P.Q.2d (BNA) 1332 (M.D. Pa. Sept. 19, 1997). (*emphasis added*).

There is no teaching or suggestion to combine Regenmortel and Tu. Even if Regenmortel and Tu were properly combined, the combination does not render claim 22 obvious because Regenmortel does not teach or suggest an immunogenic peptide that fits the description of claim 1, and TU only teaches IL-12.

It is to be noted, however, that citing references which **merely indicate that isolated elements and/or features** recited in the claims are known **is not a sufficient basis** for concluding that the combination of claimed elements would have been obvious. *Ex parte Hiyamizu* (BPAI 1988) 10 PQ. 2d 1393 (*emphasis added*).

Even if all of the elements of a claim are present in the prior art, the claim will not be obvious unless the prior art also contained, at the time the claim was filed, a motivation to combine prior art elements into the claimed invention. The conclusion that the prior art contained a motivation to combine is a conclusion of fact. *Scimed Life Sys. v. Johnson & Johnson*, 2004 U.S. App. LEXIS 510.

Obviousness requires **a suggestion of all limitations** in a claim." *CFMT, Inc. v. Yieldup Int'l Corp.*, 2003 U.S. App. LEXIS 23072 (Fed. Cir. 2003) (*emphasis added*).

To properly combine two references to reach a conclusion of obviousness, there must be some teaching, suggestion or inference in either or both of the references, or knowledge generally available to one skilled in the art, which would have led one to combine the relevant teachings of the two references. *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc. et al.* (CAFC 1985) 776 F. 2d 281, 227 USPQ 657; *Ex parte Levengood, supra.* Both the suggestion to make the claimed

composition or device or carry out the claimed process and the reasonable expectation of success must be founded in the prior art, not in applicant's disclosure. *In re Vaeck* (CAFC 1991) 947 F. 2d 488, 20 PQ. 2d 1438. The references, viewed by themselves and not in retrospect, must suggest doing what applicant has done. *In re Shaffer* (CCPA 1956) 229 F. 2d 476, 108 USPQ 326; *In re Skoll* (CCPA 1975) 523 F. 2d 1392, 187 USPQ 481.

In *re Rouffet,* the court held

> "To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court **requires the examiner to show a motivation to combine the references that create the case of obviousness**. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." In *re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998). (*emphasis added*).

Therefore, Claims 18-19, and 22 are not obvious over Regenmortel in view of either Hasegawa or Tu.

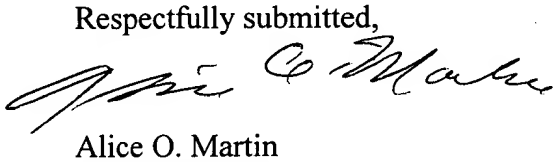
V. Conclusion and Summary

In view of the arguments presented herein, please allow all pending claims.

An interview is requested on Tuesday, October 12, 2004 at 10:30 a.m. EST. to resolve any remaining issues.

No fees are believed due at this time, however, please charge any additional deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (21417/92378).

Respectfully submitted,



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